SECTION 5. 510(K) SUMMARY

Submission Correspondent:	Instratek, Inc. 210 Spring Hill Drive Suite 130 Spring, TX 77386 USA Phone: 281-890-8020 Fax: 281-890-8068 Email: jeff@instratek.com Contact: Mr. Jeff Seavey Vice President
Date summary prepared:	February 1, 2008
Device trade name:	Sub-Talar Lok Implant
Device common name:	Subtalar Implant
Device classification name:	Screw, Fixation, Bone. HWC at 21 CFR Part 880.3040
Legally marketed device to which the device is substantially equivalent:	K032902, Futura Conical Subtalar Implant, Nexa Orthopedics K031155, Extremity Talar-Fit Implant, Osteomed.
Description of the device:	The Instratek Sub-Talar Lok Implant is designed to stabilize the subtalar joint of the hyperpronated foot. The implant is conical shaped with external threads of uniform depth and pitch. The device is cannulated for use with a guide wire. The product will be provided with a procedure kit containing: • Five (5) dilators sized 7 through 11 mm • Ten Sub-Talar Lok implants, two each of five sizes • Regular driver, 4.3mm hex head • Rescue driver, threaded

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Intended use of the device:	The Instratek Sub-Talar Lok arthroereisis implant restricts excessive subtalar pronation in all three planes, providing for a more normal subtalar joint motion in patients. The Sub-Talar Lok is intended for the following pathological conditions resulting from disease, injury, or other trauma. • Hypermobile pes valgus • Posterior tibial tendon dysfunction • Severe pronation • Subtalar instability • Hypermobile flexible congenital flat foot
Technological characteristics:	The proposed device has the same technological characteristics as the predicate devices.
Conclusions:	The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2008

Instratek, Inc.
% Mr. Jeff Seavey
210 Spring Hill Drive
Suite 130
The Woodlands, TX 77386

Re: K080280
Trade/Device Name: Sub-Talar Lok Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 1, 2008
Received: February 7, 2008

Dear Mr. Seavey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number: K080280

Device Name: Sub-Talar Lok Implant

Indications for Use: The Instratek Sub-Talar Lok arthroereisis implant restricts excessive subtalar pronation in all three planes, providing for a more normal subtalar joint motion in patients. The Sub-Talar Lok is intended for the following pathological conditions resulting from disease, injury, or other trauma.

- Hypermobile pes valgus
- Posterior tibial tendon dysfunction
- Severe pronation
- Subtalar instability
- Hypermobile flexible congenital flat foot

Prescription Use __X___ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mpm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080280